

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 523
(A-22)

Introduced by: Medical Student Section

Subject: Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices

Referred to: Reference Committee E

1 Whereas, Thirty-two million Americans, or 1 in 10, have at least one medical device¹; and
2
3 Whereas, A medical device is defined within the Food Drug & Cosmetic Act as "... an
4 instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other
5 similar or related article, including a component part, or accessory...intended for use in the
6 diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of
7 disease..., or intended to affect the structure or any function of the body...and which does not
8 achieve any of its primary intended purposes through chemical action...[and] is not dependent
9 upon being metabolized for the achievement of any of its primary intended purposes"²; and
10
11 Whereas, The Food and Drug Administration (FDA) has three regulatory classifications for
12 medical devices: Class I (minimal potential harm), Class II (moderate risk of harm), and Class III
13 (potential high risk of illness or injury)²⁻³; and
14
15 Whereas, The FDA approves the safety and efficacy of medical devices through three major
16 processes, one of which is Premarket Notification (PMN), also known as the 510(k) approval
17 pathway or 510(k) exception⁴; and
18
19 Whereas, The 510(k) approval pathway "is intended to support the FDA's public health mission
20 by meeting two important goals: making available to consumers devices that are safe and
21 effective, and fostering innovation in the medical device industry"⁵; and
22
23 Whereas, A Class II device can be cleared to market by submission and FDA review through
24 the 510(k) exception if that device is substantially equivalent to a "predicate device", even if the
25 "predicate device" had not been recently tested^{4,6,7}; and
26
27 Whereas, Using predicate devices for safety and efficacy standards may not accurately reflect
28 modern performance and safety standards⁸; and
29
30 Whereas, A number of devices approved via the 510(k) exception were later found to be less
31 efficacious than anticipated or even unsafe in their indicated usage, including transvaginal and
32 surgical meshes, metal-on-metal hip implants, and bioresorbable vascular scaffolds⁹⁻¹³; and
33
34 Whereas, Medical devices cleared through the 510(k) exception comprise more than two-thirds
35 of the products recalled by the FDA for safety concerns¹⁴; and
36
37 Whereas, There were attempts to improve the 510(k) pathway via the Safety of Untested and
38 New Devices Act of 2012 (SOUND Device Act) and again in 2019, but predicate devices have
39 remained the standard to evaluate device safety and efficacy^{15,16}; and

1 Whereas, One way to improve medical device standards is to mandate that 510(k) devices
2 demonstrate improved safety and effectiveness compared to marketed devices for the same
3 clinical purpose¹⁶; and
4

5 Whereas, Post-market surveillance is a critical component of medical device safety and
6 effectiveness because: 1) adverse events may not become apparent until the device has been
7 widely disseminated, and 2) increased emphasis on priority reviews and shortening premarket
8 approval times has decreased the standard of medical device approvals^{16,17}; and
9

10 Whereas, Current post-market surveillance only identifies a small fraction of adverse events
11 because it is based on mandated reports and passive surveillance¹⁶; and
12

13 Whereas, Post-market surveillance can be improved by giving conditional approval and
14 collecting data, including confirmatory trials¹⁶;
15

16 Whereas, Current policy (H-100.992) only outlines the AMA's position on approval processes for
17 biological drugs, but does not cover medical devices; therefore be it
18

19 RESOLVED, That our AMA support improvements to the Food and Drug Administration 510(k)
20 exception to ensure the safety and efficacy of medical devices to: (a) make more stringent
21 guidelines for which devices can qualify for the 510(k) exceptions; (b) mandate all 510(k)
22 devices demonstrate equivalent or improved safety and effectiveness compared to market
23 devices for the same clinical purpose; (Directive to Take Action) and be it further
24

25 RESOLVED, That our AMA support stronger post-market surveillance requirements of medical
26 devices, including but not limited to (a): conditional approval of devices until sufficient post-
27 market surveillance data determining device safety can be collected, followed by confirmatory
28 trials, and (b) a publicly available summary of medical devices approved under expedited
29 programs along with associated clinical trial data and list of reported adverse events; (Directive
30 to Take Action) and be it further
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32 RESOLVED, That our AMA amend policy H-100.992 to include medical devices by addition as
33 follows:
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35 **FDA, H-100.992**

36 1. Our AMA reaffirms its support for the principles that:

37 (a) an FDA decision to approve a new drug or medical device, to withdraw a drug or
38 medical device's approval, or to change the indications for use of a drug or medical
39 device must be based on sound scientific and medical evidence derived from controlled
40 trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident
41 reports as provided by statute;

42 (b) this evidence should be evaluated by the FDA, in consultation with its Advisory
43 Committees and expert extramural advisory bodies; and

44 (c) any risk/benefit analysis or relative safety or efficacy judgments should not be
45 grounds for limiting access to or indications for use of a drug or medical device unless
46 the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and post
47 market reports shows that the drug or medical device is unsafe and/or ineffective for its
48 labeled indications. (Modify Current HOD Policy)

Fiscal Note: Not yet determined

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RELEVANT AMA POLICY

Use of Remote Sensing & Monitoring Devices 1.2.9

Sensing and monitoring devices can benefit patients by allowing physicians and other health care professionals to obtain timely information about the patient's vital signs or health status without requiring an in-person, face-to-face encounter. Implantable devices can also enable physicians to identify patients rapidly and expedite access to patients' medical records. Devices that transmit patient information wirelessly to remote receiving stations can offer convenience for both patients and physicians, enhance the efficiency and quality of care, and promote increased access to care, but also raise concerns about safety and the confidentiality of patient information. Individually, physicians who employ remote sensing and monitoring devices in providing patient care should:

- (a) Determine whether using one or more such devices is appropriate in light of individual patients' medical needs and circumstances, including patients' ability to use the chosen device appropriately.
 - (b) Explain how the device(s) will be used in the patient's care and what will be expected of the patient in using the technology, and disclose any limitations, risks, or medical uncertainties associated with the device(s) and data transmission.
 - (c) Obtain the patient's or surrogate's informed consent before implementing the device in treatment. Collectively, physicians should:
 - (d) Support research into the safety, efficacy, and possible non-medical uses of remote sensing and monitoring devices, including devices intended to transmit biometric data and implantable radio frequency ID devices.
 - (e) Advocate for appropriate oversight of remote sensing and monitoring devices.
- AMA Principles of Medical Ethics: I, III, V Issued: 2016

Reprocessing of Single-Use Medical Devices H-480.959

1. Our AMA: (a) supports the Food and Drug Administration (FDA) guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" that was issued on August 2, 2000; (b) supports the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry; (c) encourages increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices; and (d) supports the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved.
 2. Our AMA strongly opposes any rules or regulations regarding the repair or refurbishment of medical tools, equipment, and instruments that are not based on objective scientific data.
- CSA Rep. 3, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Appended: Res. 217, I-17

Required Reporting of Adverse Events 8.8

Physicians' professional commitment to advance scientific knowledge and make relevant information available to patients, colleagues, and the public carries with it the responsibility to report suspected adverse events resulting from the use of a drug or medical device.

Mandated pre- and post-marketing studies provide basic safeguards for public health but are inherently limited in their ability to detect rare or unexpected consequences of use of a drug or medical device. Thus spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations are irreplaceable as a source of information about the safety of drugs and devices. As the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events. Cases in which there is clearly a causal relationship between use of a drug/device and an adverse event, especially a serious event, will be rare. Physicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship, to suspect that an adverse event has occurred. A physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to:

- (a) Communicate that information to the professional community through established reporting mechanisms.
- (b) Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention to the appropriate regulatory agency.

AMA Principles of Medical Ethics: I, V, VII Issued: 2016

Use of Wireless Radio-Frequency Devices in Hospitals H-215.972

Our AMA encourages: (1) collaborative efforts of the Food and Drug Administration, American Hospital Association, American Society for Healthcare Engineering, Association for the Advancement of Medical Instrumentation, Emergency Care Research Institute, and other appropriate organizations to develop consistent guidelines for the use of wireless radio-frequency transmitters (e.g., cellular telephones, two-way radios) in hospitals and standards for medical equipment and device manufacturers to ensure electromagnetic compatibility between radio-frequency transmitters and medical devices; and that our AMA work with these organizations to increase awareness among physicians and patients about electromagnetic compatibility and electromagnetic interference in hospital environments;

- (2) hospital administrators to work with their clinical/biomedical engineering staff, safety committees, and other appropriate personnel to adopt and implement informed policies and procedures for (a) managing the use of wireless radio-frequency sources in the hospital, particularly in critical patient care areas; (b) educating staff, patients, and visitors about risks of electromagnetic interference (EMI); (c) reporting actual or suspected EMI problems; and (d) testing medical devices for susceptibility to EMI when electromagnetic compatibility information is lacking;
- (3) medical device and electronic product manufacturers to design and test their products in conformance with current electromagnetic immunity standards and inform users about possible symptoms of electromagnetic interference (EMI). If a possibility of EMI problems affecting medical devices exists, steps should be taken to ensure that all sources of electromagnetic energy are kept at sufficient distance; and
- (4) physicians to become knowledgeable about electromagnetic compatibility and electromagnetic interference (EMI), recognize EMI as a potential problem in hospital environments, and report suspected EMI problems to the Food and Drug Administration MedWatch program or appropriate hospital personnel.

CSA Rep 4, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

Medical Device Safety and Physician Responsibility H-480.972

The AMA supports: (1) the premise that medical device manufacturers are ultimately responsible for conducting the necessary testing, research and clinical investigation and scientifically proving the safety and efficacy of medical devices approved by the Food and Drug Administration; and (2) conclusive study and development of Center for Devices and Radiological Health/Office of Science and Technology recommendations regarding safety of article surveillance and other potentially harmful electronic devices with respect to pacemaker use.

Res. 507, I-95; Res. 509, A-96; Appended: Res. 504, A-99; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: CSAPH Rep. 01, A-19

Guidelines for Mobile Medical Applications and Devices D-480.972

1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence based.
4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.

CSAPH Rep. 5, A-14; Appended: Res. 201, A-15; Appended: Res. 305, I-16; Modified: Res. 903, I-19

Interoperability of Medical Devices H-480.953

Our AMA believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation.

Res. 519, A-09; Reaffirmation: I-15; Reaffirmed: BOT Rep. 05, I-16

Medical Device "Use Before Dates" D-480.977

Our AMA will encourage the US Food and Drug Administration to clearly define and interpret the definition and meaning of the "use before date" for medical devices.

Res. 508, A-12

Access to Medical Care D-480.991

Our AMA shall work with the Centers for Medicare and Medicaid Services to maximize access to the devices and procedures available to Medicare patients by ensuring reimbursement at least covers the cost of said device or procedure.

Res. 130, A-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 1, A-14

Encouraging Alternatives to PVC/DEHP Products in Health H-135.945

Our AMA: (1) encourages hospitals and physicians to reduce and phase out polyvinyl chloride (PVC) medical device products, especially those containing Di(2-ethylhexyl)phthalate (DEHP), and urge adoption of safe, cost-effective, alternative products where available; and (2) urges expanded manufacturer development of safe, cost-effective alternative products to PVC medical device products, especially those containing DEHP.

BOT Action in response to referred for decision Res. 502, A-06; Reaffirmed: CSAPH Rep. 01, A-16

Protecting Social Media Users by Updating FDA Guidelines D-105.995

Our AMA will lobby the Food and Drug Administration to: (1) update regulations to ensure closer regulation of paid endorsements of drugs or medical devices by individuals on social media; and (2) develop guidelines to ensure that compensated parties on social media websites provide information that includes the risks and benefits of specific drugs or medical devices and off-use prescribing in every related social media communication in a manner consistent with advertisement guidelines on traditional media forms.

Res. 209, I-15

Patient Access to Treatments Prescribed by Their Physicians H-120.988

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.
Res. 30, A-88, Reaffirmed: BOT Rep. 53, A-94, Reaffirmed and Modified: CSA Rep. 3, A-97, Reaffirmed and Modified: Res. 528, A-99, Reaffirmed: CMS Rep. 8, A-02, Reaffirmed: CMS Rep. 6, A-03, Modified: Res. 517, A-04, Reaffirmation, I-07, Reaffirmed: Res. 819, I-07, Reaffirmation, A-09, Reaffirmation, I-10, Modified: BOT Rep. 5, I-14, Reaffirmed: Res. 505, A-15, [Reaffirmed: CMS Rep. 6, I-20](#); Reaffirmed: Res. 509, I-20

Registry of Implantable Devices H-480.986

It is the policy of the AMA: (1) to support the concept of a computerized national tracking system for long-term implanted devices that pose a significant risk of serious harm or death to patients if they malfunction or fail completely; (2) that such a system include the communication of the potential for malfunction or failures to the attending surgeon or physician and from the physician to the patient; and (3) to work with all involved parties to satisfactorily address this issue.

BOT Rep. JJ, A-90, Reaffirmed: Sunset Report I-00, Reaffirmed: CSAPH Rep. 1, A-10, Reaffirmed: CSAPH Rep. 01, A-20

Latex Allergy Warning H-480.970

The AMA supports the appropriate labeling of latex-containing medical devices with warnings about possible allergic reactions. The AMA strongly encourages health care facilities to provide non-latex alternatives of at least comparable efficacy alongside their latex counterparts in all areas of patient care.

Sub Res. 502, A-96, Appended Res. 504, I-97, Reaffirmed: CSAPH Rep. 3, A-07, Reaffirmed: CSAPH Rep. 01, A-17

Physicians and Clinical Trials D-460.979

Our AMA supports elimination of the use of restrictive covenants or clauses that interfere with scientific communication in agreements between pharmaceutical companies or manufacturers of medical instruments, equipment and devices, and physician researchers.

Res. 610, I-04, Modified: CSAPH Rep. 1, A-14

Availability of Professionals for Research H-460.982

(1) In its determination of personnel and training needs, major public and private research foundations, including the Institute of Medicine of the National Academy of Sciences, should consider the future research opportunities in the biomedical sciences as well as the marketplace demand for new researchers. (2) The number of physicians in research training programs should be increased by expanding research opportunities during medical school, through the use of short-term training grants and through the establishment of a cooperative network of research clerkships for students attending less research-intensive schools. Participation in research training programs should be increased by providing financial incentives for research centers, academic physicians, and medical students. (3) The current annual production of PhDs trained in the biomedical sciences should be maintained. (4) The numbers of nurses, dentists, and other health professionals in research training programs should be increased. (5) Members of the industrial community should increase their philanthropic financial support to the nation's biomedical research enterprise. Concentration of support on the training of young investigators should be a major thrust of increased

funding. The pharmaceutical and medical device industries should increase substantially their intramural and extramural commitments to meeting postdoctoral training needs. A system of matching grants should be encouraged in which private industry would supplement the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration sponsored Career Development Awards, the National Research Service Awards and other sources of support. (6) Philanthropic foundations and voluntary health agencies should continue their work in the area of training and funding new investigators. Private foundations and other private organizations should increase their funding for clinical research faculty positions. (7) The National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration should modify the renewal grant application system by lengthening the funding period for grants that have received high priority scores through peer review. (8) The support of clinical research faculty from the National Institutes of Health Biomedical Research Support Grants (institutional grants) should be increased from its current one percent. (9) The academic medical center, which provides the multidisciplinary research environment for the basic and clinical research faculty, should be regarded as a vital medical resource and be assured adequate funding in recognition of the research costs incurred.

BOT Rep. NN, A-87, Reaffirmed: Sunset Report, I-97, Reaffirmed: CSA Rep. 13, I-99, Reaffirmed: CME Rep. 4, I-08, Modified: Res. 305, A-12, Modified: CME Rep. 2, A-12

Comparative Effectiveness Research H-460.909

A. Value. Value can be thought of as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information. Quality comparative clinical effectiveness research (CER) will improve health care value by enhancing physician clinical judgment and fostering the delivery of patient-centered care.

B. Independence. A federally sponsored CER entity should be an objective, independent authority that produces valid, scientifically rigorous research.

C. Stable Funding. The entity should have secure and sufficient funding in order to maintain the necessary infrastructure and resources to produce quality CER. Funding source(s) must safeguard the independence of a federally sponsored CER entity.

D. Rigorous Scientifically Sound Methodology. CER should be conducted using rigorous scientific methods to ensure that conclusions from such research are evidence-based and valid for the population studied. The primary responsibility for the conduct of CER and selection of CER methodologies must rest with physicians and researchers.

E. Transparent Process. The processes for setting research priorities, establishing accepted methodologies, selecting researchers or research organizations, and disseminating findings must be transparent and provide physicians and researchers a central and significant role.

F. Significant Patient and Physician Oversight Role. The oversight body of the CER entity must provide patients, physicians (MD, DO), including clinical practice physicians, and independent scientific researchers with substantial representation and a central decision-making role(s). Both physicians and patients are uniquely motivated to provide/receive quality care while maximizing value.

G. Conflicts of Interest Disclosed and Minimized. All conflicts of interest must be disclosed, and safeguards developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders with such conflicts of interest do not undermine the integrity and legitimacy of the research findings and conclusions.

H. Scope of Research. CER should include long term and short-term assessments of diagnostic and treatment modalities for a given disease or condition in a defined population of patients. Diagnostic and treatment modalities should include drugs, biologics, imaging and laboratory tests, medical devices, health services, or combinations. It should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data. The priority areas of CER should be on high volume, high cost diagnosis, treatment, and health services for which there is significant variation in practice. Research priorities and methodology should factor in any systematic variations in disease prevalence or response across groups by race, ethnicity, gender, age, geography, and economic status.

I. Dissemination of Research. The CER entity must work with health care professionals and health care professional organizations to effectively disseminate the results in a timely manner by significantly expanding dissemination capacity and intensifying efforts to communicate to physicians utilizing a variety of strategies and methods. All research findings must be readily and easily accessible to physicians as well as the public without limits imposed by the federally supported CER entity. The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

J. Coverage and Payment. The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

K. Patient Variation and Physician Discretion. Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition, patient autonomy and choice may play a significant role in both CER findings and diagnostic/treatment planning in the clinical setting. As a result, sufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative.

CMS Rep. 5, I-08, Reaffirmed: Res. 203, I-09, Reaffirmation: I-10, Reaffirmed: CMS Rep. 05, I-16, Reaffirmed: CMS Rep. 4, I-19

FDA H-100.992

(1) Our AMA supports the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or post-market incident reports as provided by statute; (b) the evidence for drug approval should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies, as appropriate; (c) expedited programs for drug approval serve the public interest as long as sponsors for drugs that are approved based on surrogate endpoints or limited evidence conduct confirmatory trials in a timely fashion to establish the expected clinical benefit and predicted risk-benefit profile; (d) confirmatory trials for drugs approved under accelerated approval should be planned at the time of expedited approval; (e) the FDA should pursue having in place a systematic process to ensure that sponsors adhere to their obligations for conducting confirmatory trials; (f) any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and post-market reports shows that the drug is unsafe and/or ineffective for its labeled indications; and (g) FDA should make the annual summary of drugs approved under expedited programs more readily available and consider adding information on confirmatory clinical trials for such drugs to the drugs trials snapshot. (2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation. (3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

Res. 119, A-80, Reaffirmed: CLRPD Rep. B, I-90, Reaffirmed: Sunset Report, I-00, Reaffirmation, A-06, Appended: Sub. Res. 509, A-06, Reaffirmation: I-09, Reaffirmation: I-10, Modified: CSAPH Rep. 2, I-18, Modified: CSAPH Rep. 02, I-19 Reaffirmed: BOT Rep. 5, I-20